UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,999	09/20/2001	Steven C. Barash	PT086P1	1712

22195 7590 12/23/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,999	BARASH ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10, 14, 15 and 21, drawn to nucleic acid, vector, method of making recombinant host cell, recombinant host cell, method of making polypeptide and gene, classified in class 435, subclass 69.1.

   II. Claims 11, 12 and 16, drawn to polypeptide, classified in class 530, subclass 350.

   III. Claim 13, drawn to antibody, classified in class 530, subclass 387.1.

   IV. Claim 17, drawn to method for preventing, treating or ameliorating a medical condition, classified in class 514, subclass 12 when the polypeptide is used or classified in class 514, subclass 44 when the polynucleotide is used.

   V. Claim 18, drawn to method of diagnosing by determining a mutation in nucleic acid, classified in class 435, subclass 6.

   VI. Claim 19, drawn to method of diagnosing by determining the amount of expression of polypeptide, classified in class 435, subclass 7.1.

   VII. Claim 20, drawn to method of identifying binding portion of polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to method of identifying an activity by expressing nucleic acid, classified in class 435, subclass 6.

IX. Claim 23, drawn to binding partner identified by the process of claim 20, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

3. Invention I is related to Invention II by virtue of the fact that the nucleic acid codes for the protein. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid and the protein are related, since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, nucleic acid can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

4. Invention I and Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

5. Invention I and Inventions IV, V and VIII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid could be used in a materially different process such as a method of making polypeptide.

6. Invention I is related to Inventions VI and VII, respectively, by virtue of the fact that the protein used in the method of Invention VI is encoded by the nucleic acid. The inventions are distinct, however because the DNA is not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

7. Invention I and Invention IX are related by virtue of the protein that is encoded by the nucleic acid and necessary for the identification of the binding partner. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

8. Invention II is related to Invention III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions

because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

9. Invention II and Inventions IV, VI and VII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide could be used in a materially different process such as a method of making antibodies.

10. Invention II is related to Inventions V and VIII by virtue of the fact that the protein is encoded by the nucleic acid used in the methods of Inventions V and VIII. The inventions are distinct, however because the protein is not used in either the method of diagnosing or the method of identifying. Therefore, the inventions are distinct.

11. Invention II differs in structure and function from Invention IX. Therefore, Invention IX is patentably distinct from Invention II.

12. Invention III is not used in the methods of Inventions IV-VIII. Therefore, Inventions IV-VIII are patentably distinct from Invention III.

13. Invention III differs in structure and function from Invention IX. Therefore, Invention IX is patentably distinct from Invention III.

14. Inventions IV, V and VIII are related in that each method requires the use of the nucleic acid of Invention I. However, the steps and end points of the methods are wholly different and therefore Inventions IV, V and VIII are patentably distinct.

15. Inventions IV, VI and VII are related in that each method requires the use of the polypeptide of Invention II. However, the steps and end points of the methods are wholly different and therefore Inventions IV, VI and VII are patentably distinct.

16. Inventions V and VI, VI and VIII, and VII and VIII, respectively, require different products and steps and have different endpoints. Therefore, Inventions V and VI are patentably distinct, Inventions VI and VII are patentably distinct and Inventions VII and VIII are patentably distinct.

17. Invention IX is not used in Inventions IV, V, VI or VIII. Therefore, Inventions IV, V, VI and VIII are patentably distinct from Invention IX.

18. Inventions VII and IX are related as process of identifying and product identified. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to identify other and materially different products or (2) that the product as claimed can be identified by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be identified by another and materially different process such as an activity assay.

19. Furthermore, the presence of multiple polynucleotide sequences and polypeptide sequences in Inventions I and II, each with a different SEQ ID NO: X or Y, respectively, and a different clone number Z allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. THIS IS NOT AN ELECTION OF SPECIES REQUIREMENT.

Applicant is advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all

claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

21. A telephone call was made to Mark Hyman on December 15, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

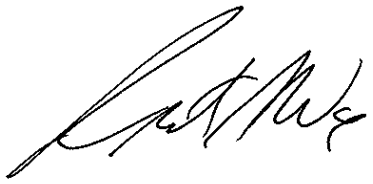
22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (703) 308-4471. After January 8, 2004 the examiner's telephone number will be (571)272-0623.

The examiner can normally be reached Monday - Friday, from 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Robert A. Wax
Primary Examiner
Art Unit 1653